FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE
(Rev. 2-32) PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
1146-4 DIV/CIP IISERIAL NO.
09/916,858INFORMATION DISCLOSURE
STATEMENT BY APPLICANTAPPLICANT
Shults et al.

CONFIRMATION NO.

(Use several sheets if necessary)

FILING DATE
July 27, 2001

GROUP

RECEIVED
FEB 15 2002
TC 1700

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
M	4,353,888	10/12/82	Sefton		11	
	4,431,004	02/14/84	Bessman et al.		11	
	4,436,094	03/13/84	Cerami		11	
	4,453,537	06/12/84	Spitzer		11	
	4,484,987	11/27/84	Gough		11	
	4,686,044	08/11/87	Behnke et al.		11	
	4,703,756	11/03/87	Gough et al.		11	
	4,757,022	07/12/88	Shults et al.		11	
	4,759,828	07/26/88	Young et al.		11	
	4,787,398	11/29/88	Garcia et al.		11	
	4,803,243	02/07/89	Fujimoto et al.		11	
	4,823,808	04/25/89	Clegg et al.		11	
	4,890,620	01/02/90	Gough		11	
	4,902,294	02/20/90	Gosserez		11	
	4,994,167	02/19/91	Shults et al.		11	
	5,165,407	11/24/92	Wilson et al.		11	
	5,190,041	03/02/93	Palti		11	
M	5,314,471	05/24/94	Brauker et al.		11	

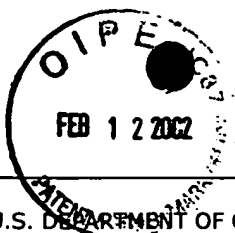
EXAMINER

Nasser

DATE CONSIDERED

3/15/04

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant.

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE
(Rev. 2-32) PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
1146-4 DIV/CIP IISERIAL NO.
09/916,858INFORMATION DISCLOSURE
STATEMENT BY APPLICANTAPPLICANT
Shults et al.

CONFIRMATION NO.

(Use several sheets if necessary)

FILING DATE
July 27, 2001

GROUP

101700

FEB 15 2002

RECEIVED

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
Rgn	5,321,414	06/14/94	Alden et al.			
	5,322,063	06/21/94	Allen et al.			
	5,344,454	09/06/94	Clarke et al.			
	5,380,536	01/10/95	Hubbell et al.			
	5,390,671	02/21/95	Lord et al.			
	5,391,250	02/21/95	Cheney, II et al.			
	5,417,395	05/23/95	Fowler et al.			
	5,421,923	06/06/95	Clarke et al.			
	5,431,160	07/11/95	Wilkins			
	5,453,278	09/26/95	Chan et al.			
	5,462,064	10/31/95	D'Angelo et al.			
	5,469,846	11/28/95	Khan			
	5,476,094	12/19/95	Allen et al.			
	5,497,772	03/12/96	Schulman et al.			
	5,538,511	07/23/96	Van Antwerp			
	5,545,223	08/13/96	Neuenfeldt et al.			
	5,549,675	08/23/96	Neuenfeldt et al.			
	5,569,186	10/29/96	Lord et al.			

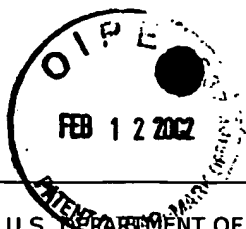
EXAMINER

Nasser

DATE CONSIDERED

3/15/04

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant.

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE
(Rev. 2-32) PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
1146-4 DIV/CIP IISERIAL NO.
09/916,858INFORMATION DISCLOSURE
STATEMENT BY APPLICANTAPPLICANT
Shults et al.

CONFIRMATION NO.

(Use several sheets if necessary)

FILING DATE
July 27, 2001

GROUP

TC 1700

FEB 15 2002

RECEIVED

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
M	5,569,462	10/29/96	Martinson et al.	11	11	
	5,578,463	11/26/96	Berka et al.	11	11	
	5,593,440	01/14/97	Brauker et al.	11	11	
	5,653,756	08/05/97	Clarke et al.	11	11	
	5,660,163	08/26/97	Schulman et al.	11	11	
	5,713,888	02/03/98	Neuenfeldt et al.	11	11	
	5,733,336	03/31/98	Neuenfeldt et al.	11	11	
	5,741,330	04/21/98	Brauker et al.	11	11	
	5,777,060	07/07/98	Van Antwerp	11	11	
	5,782,912	07/21/98	Brauker et al.	11	11	
	5,800,529	09/01/98	Brauker et al.	11	11	
	5,807,406	09/15/98	Brauker et al.	11	11	
	5,882,354	03/16/99	Brauker et al.	11	11	
	5,882,494	03/16/99	Van Antwerp	11	11	
	5,964,261	10/12/99	Neuenfeldt et al.	11	11	
	5,985,129	11/16/99	Gough et al.	11	11	
	6,001,067	12/14/99	Shults et al.	11	11	
	6,122,536	09/19/00	Sun et al	11	11	

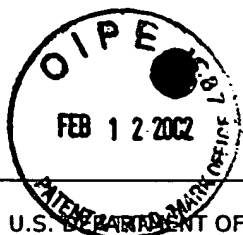
EXAMINER

Nasser

DATE CONSIDERED

3/15/04

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant.

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE
(Rev. 2-32) PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
1146-4 DIV/CIP IISERIAL NO.
09/916,858INFORMATION DISCLOSURE
STATEMENT BY APPLICANTAPPLICANT
Shults et al.

CONFIRMATION NO.

(Use several sheets if necessary)

FILING DATE
July 27, 2001

GROUP

TC 1700

FEB 15 2002

RECEIVED

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
M	6,144,869	11/07/00	Berner et al.			
	6,175,752	01/16/01	Say et al.			
	6,180,416	01/30/01	Kurnik et al.			
	6,200,772	03/13/01	Vadgama et al.			
	6,201,980	03/13/01	Darrow et al.			
	6,208,894	03/27/01	Schulman et al.			
	6,212,416	04/03/01	Ward et al.			
	6,223,080	04/24/01	Thompson			
	6,223,083	04/24/01	Rosar			
	6,230,059	05/08/01	Duffin			
	6,233,471	05/15/01	Berner et al.			
	6,254,586	07/03/01	Mann et al.			
	6,256,522	07/03/01	Schultz			
	6,259,937	07/10/01	Schulman et al.			
	6,272,364	08/07/01	Kurnik			
	6,272,382	08/07/01	Faltys et al.			
M	6,299,578	10/09/01	Kurnik et al.			
	6,309,351	10/30/01	Kurnik et al.			

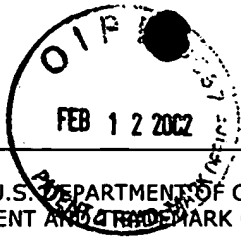
EXAMINER

Nasser

DATE CONSIDERED

B/15/04

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant.

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE
(Rev. 2-32) PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
1146-4 DIV/CIP IISERIAL NO.
09/916,858INFORMATION DISCLOSURE
STATEMENT BY APPLICANTAPPLICANT
Shults et al.

CONFIRMATION NO.

(Use several sheets if necessary)

FILING DATE
July 27, 2001

GROUP

RECEIVED
FEB 15 2002
TO 1700

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
~	6,326,160	12/04/01	Dunn et al.			
~	6,329,161	12/11/01	Heller et al.			

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION	
						YES	NO
~	WO 90/00738	01/25/90	PCT				
	WO 92/07525	05/14/92	PCT				
	WO 92/13271	08/06/92	PCT				
	WO 93/19701	10/14/93	PCT				
	WO 94/22367	10/13/94	PCT				
	WO 96/01611	01/25/96	PCT				
	WO 96/32076	10/17/96	PCT				
	WO 96/36296	11/21/96	PCT				
	WO 01/20019	03/22/01	PCT				
	WO 01/20334	03/22/01	PCT				
	WO 01/34243	05/17/01	PCT				
	WO 01/58348	08/16/01	PCT				

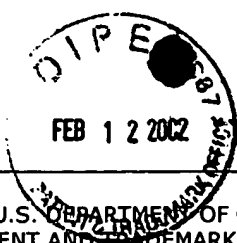
EXAMINER

Nasser

DATE CONSIDERED

3/15/04

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant.

RECEIVED
FEB 15 2002FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE
(Rev. 2-32) PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
1146-4 DIV/CIP IISERIAL NO.
09/916,858INFORMATION DISCLOSURE
STATEMENT BY APPLICANTAPPLICANT
Shults et al.

CONFIRMATION NO.

(Use several sheets if necessary)

FILING DATE
July 27, 2001

GROUP

FOREIGN PATENT DOCUMENTS

							TRANSLATION
m		WO 01/68901	09/20/01	PCT			
		WO 01/69222	09/20/01	PCT			
		WO 01/88524	11/22/01	PCT			
n		WO 01/88534	11/22/01	PCT			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

m		Updike et al., "Laboratory Evaluation of New Reusable Blood Glucose Sensor," <i>Diabetes Care</i> , 11:801-807 (1988).
		Moatti-Sirat et al., "Towards Continuous Glucose Monitoring: In Vivo Evaluation of a Miniaturized Glucose Sensor Implanted for Several Days in Rat Subcutaneous Tissue," <i>Diabetologia</i> 35:224-30 (1992).
		Armour et al., "Application of Chronic Intravascular Blood Glucose Sensor in Dogs," <i>Diabetes</i> 39:1519-26 (1990).
		Woodward, "How Fibroblasts and Giant Cells Encapsulate Implants: Considerations in Design of Glucose Sensor," <i>Diabetes Care</i> 5:278-281 (1982).
		Bindra et al., "Design and In Vitro Studies of a Needle-Type Glucose Sensor for Subcutaneous Monitoring," <i>Anal. Chem.</i> 63:1692-96 (1991).
n		Shults et al., "A Telemetry-Instrumentation System for Monitoring Multiple Subcutaneously Implanted Glucose Sensors," <i>IEEE Trans, Biomed. Eng.</i> 41:937-942 (1994).

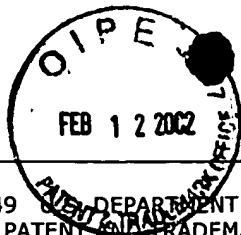
EXAMINER

Nasser

DATE CONSIDERED

3/15/02

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant.

FORM PTO-1449 DEPARTMENT OF COMMERCE
(Rev. 2-32) PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
1146-4 DIV/CIP IISERIAL NO.
09/916,858INFORMATION DISCLOSURE
STATEMENT BY APPLICANTAPPLICANT
Shults et al.

CONFIRMATION NO.

(Use several sheets if necessary)

FILING DATE
July 27, 2001

GROUP

RECEIVED
FEB 15 2002
TG 4700

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

NS		Phillips and Smith, "Biomedical Applications of Polyurethanes: Implications of Failure Mechanisms," <i>J. Biomat. Appl.</i> 3:202-227 (1988).
		Stokes, "Polyether Polyurethanes: Biostable or Not?," <i>J. Biomat. Appl.</i> 3:228-259 (1988).
		Udike et al., "Enzymatic Glucose Sensors: Improved Long-Term Performance In Vitro and In Vivo," <i>Am.Soc. Artificial Internal Organs</i> 40:157-163 (1994).
		Udike et al., "Implanting the Glucose Enzyme Electrode: Problems, Progress, and Alternative Solutions," <i>Diabetes Care</i> 5:207-21 (1982).
		Rhodes et al., "Prediction of Pocket-Portable and Implantable Glucose Enzyme Electrode Performance from Combined Species Permeability and Digital Simulation Analysis," <i>Anal. Chem.</i> 66:1520-1529 (1994).
		Tse and Gough, "Time-Dependent Inactivation of Immobilized Glucose Oxidase and Catalase," <i>Biotechnol. Bioeng.</i> 29:705-713 (1987).
		Gilligan et al., "Evaluation of a Subcutaneous Glucose Sensor Out to 3 Months in a Dog Model," <i>Diabetes Care</i> 17:882-887 (1994).
		McKean and Gough, "A Telemetry-Instrumentation System for Chronically Implanted Glucose and Oxygen Sensors," <i>IEEE Trans. Biomed. Eng.</i> 35:526-532 (1988).
		Shichiri et al., "Telemetry Glucose Monitoring Device with Needle-Type Glucose Sensor - A Useful Tool for Blood Glucose Monitoring in Diabetic Individuals," <i>Diabetes Care</i> 9:298-301 (1986).
NS		Lyman, "Polyurethanes. I. The Solution Polymerization of Diisocyanates with Ethylene Glycol," <i>J. Polymer Sci.</i> 45:49 (1960).

EXAMINER

Nasser

DATE CONSIDERED

8/15/04

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant.

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE
(Rev. 2-32) PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.
1146-4 DIV/CIP II

SERIAL NO.
09/916,858

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

APPLICANT
Shults et al.

CONFIRMATION NO.

(Use several sheets if necessary)

FILING DATE
July 27, 2001

GROUP

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

M		DuPont ¹ Dimension AR [®] (Catalog).
		Direct 30/30 [®] meter (Markwell Medical) (Catalog).
		Fischer et al., "Oxygen Tension at the Subcutaneous Implantation Site of Glucose Sensors," <i>Biomed. Biochem.</i> 11/12, 965-972 (1989).
A		Brauker et al., "Neovascularization of Synthetic Membranes Directed by Membrane Microarchitecture," <i>Journal of Biomedical Materials Research</i> 29:1517 (1995).
		Abstract presented by James Brauker, Ph.D., "Neovascularization of Cell Transplantation Devices: Membrane Architecture-Driven and Implanted Tissue-Driven Vascularization," Baxter Healthcare Corp.
		Brauker et al., "Local Inflammatory Response Around Diffusion Chambers Containing Xenografts", <i>Transplantation</i> , Vol. 61, 1671-1677, No. 12, June 27, 1996.

EXAMINER

Nasser

DATE CONSIDERED

3/15/04

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant.

RECEIVED
FEB 15 2002
TC 1700